510(K) Summary, K100250

This 510(k) summary for Xcerām® material is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: XceramUSA

Contact: Solomon Menashi
34 Halcyon Road
Newton MA 02459 USA
Tel 1-617-331-9210

APR - 8 2010

Manufacturer: Xceram® (Luxembourg)

Preparation Date: January 19, 2010

Device Name: Xceram®®
Common Name: Dental Frame Material for Dental Prosthesis
Classification Information:
Porcelain, powder for clinical use
CFR: 21 CFR 872.6660
Class: Class II medical device
Product Code: EIH
Panel: Dental

Predicate devices: K070537 ZirBlock®, CDL Technologies; K092513 Rainbow Block, Genoss Co. Ltd.; K092630 Zirox, Zencera, Inc.

Device description: Xceram® is a pre-formed material for use by dental laboratories in filling orders/prescriptions for dental prosthetics

Indications: Xceram® is used in the manufacture of dental prosthetics: crowns, bridges, inlays, and onlays.

Performance Data: None required. The claim of substantial equivalence is based on comparisons of formulations, mechanical characteristics, and intended uses of the devices to legally marketed predicates and to the IDENTIFICATION of porcelain powders in 21 CFR 872.6660.

CONCLUSION: Based on the information in the premarket notification, Xceram®USA believes that the Xceram® device is substantially equivalent to cited legally marketed predicates and to the IDENTIFICATION in the classifying regulation (21 CFR 872.6660).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

XceramUSA
C/O Mr. Daniel Kamm
Principal Consultant
Kamm & Associates
8726 Ferrara Court
Naples, Florida 34114

APR - 8 2010

Re: K100250
Trade/Device Name: Xceram®
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Codes: EIH
Dated: January 20, 2010
Received: January 27, 2010

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.\

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100250

Device Name: Xceram®

Indications For Use:

Used in the manufacture of dental prosthetics: crowns, bridges, inlays, and onlays.

Prescription Use X AND/OR Over-The-Counter Use ___.
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

R S Betz DDS for Dr. K. P. Mudy

Division Sign-Off)
)ivision of Anesthesiology, General Hospital
ıfection Control, Dental Devices

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